IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WALTER SHUKER and VIVIAN SHUKER Plaintiffs, v. SMITH & NEPHEW, PLC and SMITH & NEPHEW, INC. Defendants.	CIVIL ACTION NO.

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, Defendants Smith & Nephew, PLC and Smith & Nephew, Inc. (collectively the "Defendants") hereby give notice of removal of this action, which was filed in the Court of Common Pleas of Philadelphia County, Pennsylvania, to the United States District Court for the Eastern District of Pennsylvania. As grounds for removal, Defendants aver as follows:

1. Defendants remove this case on the basis of diversity jurisdiction because there is complete diversity of citizenship among the parties to this litigation and the amount in controversy exceeds $75,000, exclusive of interest and costs. See 28 U.S.C. § 1332(a)(1) ("[t]he district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different states.").

BACKGROUND

2. Plaintiffs filed their Complaint in the Court of Common Pleas of Philadelphia County, on or about September 25, 2013, under Case No. 130501136.

3. On or about October 4, 2013, Defendant Smith & Nephew, Inc. received a copy of Plaintiffs' Complaint. A true and correct copy of the Complaint is attached hereto as **Exhibit 1.**

4. Defendant Smith & Nephew, PLC has not been properly served with Plaintiffs' Complaint, but nevertheless joins in this removal, without waiving its objections based on inadequate service.

5. In the Complaint, Plaintiffs assert claims for: (1) negligence; (2) strict product liability; (3) breach of express warranty; (4) breach of implied warranties of merchantability; (5) fraud; and (6) loss of consortium. Complaint ¶¶ 49-118.

TIMELINESS OF REMOVAL

6. This Notice of Removal is timely in that it is filed within 30 days from the date Defendants first received a copy of the Complaint. See 28 U.S.C. § 1446(b).

DIVERSITY OF CITIZENSHIP

7. Complete diversity of citizenship exists in this matter.

8. Plaintiffs allege that they are citizens of the Commonwealth of Pennsylvania. See Complaint ¶¶ 1, 2.

9. Defendant Smith & Nephew, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located in Memphis,

Tennessee. See 28 U.S.C. § 1332(c)(1) ("a corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business").

10. Defendant Smith & Nephew, PLC is a public limited company organized under the laws of the United Kingdom, with a principal place of business located in the United Kingdom.

AMOUNT IN CONTROVERSY

11. Plaintiffs' Complaint seeks damages in "an amount greater than $50,000," in addition to all remedies provided by law, including punitive damages. See Complaint, Prayer for Relief, Counts I, II, III; Complaint at ¶ 114. Where, as here, the Plaintiffs do not specifically allege that the amount in controversy is less than the jurisdictional amount, the case will not be remanded unless it appears to a legal certainty that the Plaintiffs cannot recover the jurisdictional amount specified in 28 U.S.C. § 1332(a). See Federico v. Home Depot, 507 F.3d 188, 197 (3d Cir. 2007).

12. Plaintiffs' Complaint alleges that as a result of Defendants' acts and omissions, "Plaintiff Walter Shuker was and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, as well as other severe and permanent health consequences." Complaint ¶¶ 59, 83, 93, 103. Further, Plaintiffs allege that Walter Shuker has incurred "medical, health, incidental and related expenses" and will require future "medical and/or hospital care, attention, and services" as a result of Defendants acts or omissions. Id. at ¶¶ 60, 84, 94, 104.

13. Additionally, Plaintiffs' Complaint alleges that as a result of Defendants actions, "Plaintiff Walter Shuker has been caused to suffer great mental and emotional distress" and "Plaintiff Vivian Shuker has been caused to suffer loss of consortium, marital services and/or companionship of her spouse." Id. at ¶¶ 116, 118.

14. Given the nature and extent of Plaintiffs' alleged injuries and damages, Plaintiffs' Complaint places at issue more than $75,000, exclusive of interests and costs.

15. Plaintiffs' claim for damages therefore exceeds the requisite amount in controversy for purposes of diversity jurisdiction under 28 U.S.C. § 1332(a).

ALL PROCEDURAL PREREQUISITES HAVE BEEN MET

16. Pursuant to 28 U.S.C. § 1441(a) and 28 U.S.C. § 1446(a), Defendants are filing this Notice of Removal in the federal district court embracing the state court where the Plaintiffs' Complaint was filed.

17. Pursuant to 28 U.S.C. § 1446(d), Defendants will give written notice of the filing of this Notice of Removal to Plaintiffs, and will file a copy of this Notice of Removal with the Prothonotary of the Court of Common Pleas of Philadelphia County, Pennsylvania.

18. Based upon the foregoing, this Court has jurisdiction over this matter, and the claims are properly removed to this Court.

WHEREFORE, Defendants Smith & Nephew, PLC and Smith & Nephew, Inc. request that this action proceed in the United States District Court for the Eastern District of Pennsylvania, as an action properly removed thereto.

Respectfully submitted,

Michael T. Scott
Attorney ID No. 23882
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103
Phone: (215) 851-8248
mscott@reedsmith.com

James B. Irwin (*pro hac vice forthcoming*)
Camala E. Capodice (*pro hac vice forthcoming*)
Irwin Frichie Urquhard & Moore LLC
400 Poydras Street, Suite 2700
New Orleans, LA 70130
Phone: (504) 310-2196
jirwin@irwinllc.com
ccapodice@irwinllc.com

Dated: October 22, 2013

Attorneys for Defendants, Smith & Nephew, PLC and Smith & Nephew, Inc.

CERTIFICATE OF SERVICE

I, Michael T. Scott, do hereby certify that a true and correct copy of the foregoing Notice of Removal, together with supporting exhibits, was served by first class U.S. mail to the below listed counsel on this 22nd day of October, 2013:

Eric Zajac, Esq.
1835 Market Street, 26th Floor
Philadelphia, PA 19103

Attorney for Plaintiffs

Michael T. Scott

EXHIBIT A

ZAJAC, ARIAS & TRICHON, P.C.
TEAM LAWYERS.COM

BY: Eric G. Zajac, Esquire
Attorney I.D. No. 66003
Eric@TeamLawyers.com
1835 Market Street, Suite 2626
Philadelphia, PA 19103
(215) 575.7615; (215) 575.7640 (Fax)

Attorney for Plaintiff
www.TeamLawyers.com

WALTER SHUKER and VIVIAN SHUKER, h/w 245 State Street Hamburg, PA 19526	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY
v.	:	CIVIL LAW ACTION
SMITH & NEPHEW PLC 15 Adam Street London WC2N 6LA, UK And SMITH & NEPHEW, INC. 150 Minuteman Road Andover, Massachussets 01810	:	MAY TERM, 2013 NO. 1136 **MAJOR JURY** **TRIAL DEMANDED**

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court with only such further notice to you as may be required by law, for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE, OR IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TEL: (215) 238-6333

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las piginas siguientes, usted tiene veinte (20) dias de plazo al partir de las demanda y la nonficacion, llace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demands en contra de su persona. Sea avisado que si ustedno se defiendo la corta tomara medidas y puede continuar la demanda en contra suya sin previo aviso o nonficacion. Ademis, la corta puede decidir a favor del demandante y requiere que usted compla con indas las provisiones de estra demanda Usted puede perder dinero o sus propiedades u otius derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOCADO IMMEDIATAMENTE SI NO TIENE ABOCADO O SI NO TIENE EL DINERO SUFICIENTE DE PACSR TEL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERICUAR DONDE SE PUEDE CONSECUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE
FILADELFIA, SERVICIO DE REFERENICA
ONE READING CENTER
FILADELFIA, PA 19107
E INFORMACION LEGAL TEL: (215) 238-6333

ZAJAC, ARIAS & TRICHON, P.C.
TEAM LAWYERS FOR CLIENTS

BY: Eric G. Zajac, Esquire
Attorney I.D. No. 66003
Eric@TeamLawyers.com
1835 Market Street, Suite 2626
Philadelphia, PA 19103
(215) 575.7615; (215) 575.7640 (Fax)

Attorney for Plaintiff
www.TeamLawyers.com

WALTER SHUKER and VIVIAN SHUKER, h/w 245 State Street Hamburg, PA 19526	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY
	:	CIVIL LAW ACTION
v.	:	
	:	MAY TERM, 2013
SMITH & NEPHEW PLC 15 Adam Street London WC2N 6LA, UK	:	NO. 1136
And	:	**MAJOR JURY**
SMITH & NEPHEW, INC. 150 Minuteman Raod Andover, Massachusetts 01810	:	**TRIAL DEMANDED**

COMPLAINT

AND NOW, come the Plaintiffs Walter and Vivian Shuker by and through their attorneys Eric G. Zajac, Esquire, ZAJAC, ARIAS & TRICHON, P.C., and file and serve upon the Defendants the following Complaint, alleging the following:

1. Plaintiff Walter Shuker is an adult individual residing at 245 State Street Hamburg, PA 19526.

2. Plaintiff Vivian Shuker is an adult individual residing at 245 State Street Hamburg, PA 19526 and at all material times was and is the lawful wife of Walter Shuker.

3. Defendant Smith & Nephew PLC is a public limited liability company incorporated in the United Kingdom and regularly doing business in the United States, including in Philadelphia, Pennsylvania.

4. Defendant Smith & Nephew. Inc. is a corporation duly incorporated in the state of Delaware with corporate headquarters at 150 Minuteman Road Andover, Massachusetts and 1450 Brooks Road Memphis, Tennessee. Smith & Nephew is registered to do business in the Commonwealth of Pennsylvania, and regularly does business in Philadelphia.

5. At all times relevant hereto, Defendant Smith & Nephew PLC wholly owned and is the parent corporation of Defendant Smith & Nephew, Inc.

6. Defendant Smith & Nephew PLC is a company engaged in the business of designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the R3 Acetabular System, including its metal liner, containing cobalt and chromium.

7. Defendant Smith & Nephew, Inc. is a corporation engaged in the business of designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the R3 Acetabular System, including its metal liner, containing cobalt and chromium.

8. At all times mentioned in this complaint, the Defendants designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold a hip replacement system, defective in its design, defective in its warnings, and defective in its manufacture, known as the R3 Acetabular System. The R3 Acetabular System was sold to surgeons and hospitals in Pennsylvania and elsewhere, and implanted in thousands of patients, including Plaintiff Walter Shuker.

9. The R3 Acetabular System is a hip replacement system, and its components serve as a substitute for the bones of the hip, including the femoral head, the ball-shaped bone at the top of the femur (also known as the thigh bone) and other portions of the femur.

10. In contrast, hip "resurfacing" systems preserve the femoral head. In hip resurfacing systems, overlays of metal or ceramic are placed over the femoral head. A cup replaces the damaged surface of a hip socket. A "cap" covers the femoral head. The Defendants' earlier "Birmingham" system is a type of hip resurfacing system. The R3 Acetabular System is not a hip resurfacing system.

11. The R3 Acetabular System is not a Class III Medical Device as that term is defined by the Medical Device Amendments of 1976 ("MDA") and decisions construing the MDA.

12. The metal liners of the R3 Acetabular Systems, known as R3 optional metal liners, are not Class III Medical Devices as that term is defined by the MDA and decisions construing the MDA.

13. To medical device manufacturers, such as Defendants, who seek it, the United States Food and Drug Administration ("FDA") grants what is known as Pre-Market Approval ("PMA") for a device intended to be sold. As the United Supreme Court describes it:

> Premarket approval is a "rigorous" process. A manufacturer must submit what is typically a multivolume application. FDA, Device Advice--Premarket Approval (PMA) 18, http:// www. fda. gov/ cdrh/ devadvice/ pma/ printer, html. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(l). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(l)(G). The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," § 360e(d). The agency must "weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C); *See also Riegel v. Medtronic. Inc.*, 552 U.S. 312, 317-318 (U.S. 2008).

14. The R3 Acetabular System did not receive Pre-Market Approval from the FDA.

15. The Defendants did not seek Pre-Market Approval from the FDA for the R3 Acetabular System.

16. Before being introduced to market, the R3 Acetabular System and its components were, instead, subjected to only a cursory review by the FDA.

17. Defendants submitted, for their R3 Acetabular System, "premarket notification to the FDA, pursuant to 21 U.S.C. § 360(k). This process is also referred to as the § 510(k) process after the number in the section of the original act. The FDA spends approximately twenty hours on this review process." *See, Medtronic v. Lohr* 518 U.S. 470, 334 (U.S. 1996).

18. On or about May 10, 2007, Defendants submitted a "510(k)" summary for the Acetabular System known as "Reflection 3" or "R3" to the FDA, and acknowledged that the system was accurately categorized as being encompassed by Regulatory Class II.

19. Defendants represented to the FDA that the R3 Acetabular System was a Class II device, "indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJDI or any of its composite diagnoses of osteoarthritis, osteonecrosis, avascular necrosis, post traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant."

20. Defendants represented that the R3 Acetabular System was "substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976." On June 6, 2007 the FDA "signed off" on the notification.

21. Having previously filed 510(k) notification, on March 6, 2008, the Defendants announced what they purported to be "a revolution in hip motion... the global launch of the R3

Acetabular System, an advanced multi-bearing acetabular cup system used in total hip replacement procedures."

22. Seeking credibility, defendants announced the "launch" at the 75th annual American Academy of Orthopaedic Surgeons (AAOS) in San Francisco, California.

23. Defendants represented to the consumer public, the medical profession and to the healthcare industry that the R3 Acetabular System was safe, effective and more beneficial to patients than other hip replacement systems.

24. "The R3 System is another example of our continuum of care in action. A surgeon now has more options to treat the patient and when combined with our excellent hip stems, the R30 system presents a high performance option that fits nicely into our growing portfolio of products for active patients," said Joseph DeVivo, a high ranking official of the Defendants.

25. In promotional materials and press releases Defendants included the statements of orthopedic surgeons, praising the system:

> "The R3 Acetabular system will now give me the flexibility to tailor the implant to each of my patients," said designer surgeon, Stephen McMahon, of the Malabar Orthopaedic Clinic in Windsor, Australia. "This range of options allows me to provide the most suitable surgical solution for each individual, enabling patients to realize their best possible outcome."

26. The R3 Acetabular system also came with a metal liner. In hip replacement systems, a liner is the bearing surface, or cup, that the head of an artificial hip rotates in. The surfaces can be constructed of metal, ceramics and/or plastics.

27. The femoral head replacement component of the R3 Acetabular System is what is known as a "bipolar head", and, according to the Defendants, is constructed of cobalt chromium alloy. The Defendants describe the bipolar head's construction and composition in R3 Acetabular System literature.

28. On February 27, 2009, the Defendants introduced an optional "metal liner" for the R3 Acetabular System. The liner employed chrome and cobalt "technology." According to the Defendants' press release of the introduction:

> "The multi-bearing cup, in addition to providing intraoperative flexibility for surgeons, provides solutions designed to reduce wear and the subsequent need for revision surgery. Its range of inserts accommodates larger head sizes and is optimized to help the R3 system achieve joint stability and a greater range of motion. By utilizing disposable trial liners and a single set of instruments for all bearings, the R3 Acetabular System gives surgeons simplicity in the operating room and confidence in a stable, multi-bearing system."

29. The optional metal liner component within the R3 Acetabular System was constructed, substantially, of cobalt and chromium.

30. The metal liner of the R3 Acetabular System was coated with cobalt and chromium.

31. The outer surface of the metal liner of the R3 Acetabular system is cobalt and chromium.

32. The metal liner would "interface with" or "house" the metal ball (femoral head replacement) of the R3 Acetabular System. Because of this interface, the combination of metal components, the cobalt and chromium femoral head and the cobalt and chromium liner, was and is referred to as a "metal on metal bearing couple" or "metal on metal" system.

33. Despite the statements made by the Defendants to the contrary, the R3 acetabular system was prone to wearing down and releasing metallic debris into the body of the user causing adverse health effects including, but not limited to: bone chipping, bone fractures, tissue damage, chronic pain, metalossis and the need for revision surgery to replace the R3 Acetabular system.

34. On June 2, 2012, the Defendants announced that they had "chosen to withdraw the optional metal liner component within the R3 Acetabular System."

35. Defendants explained that "Smith & Nephew... has chosen to withdraw the optional metal liner component within the R3 Acetabular System as a precautionary measure following a review of the most recent data. Data collected, including data from the Australian and UK patient registries, indicated the metal liner component within the R3 Acetabular System is not performing as well as we would like."

36. "We regularly review the effectiveness of our products and are not satisfied with the clinical results of this component," acknowledged Andy Weymann, Smith & Nephew's chief medical officer.

37. The equivalent of the FDA in the United Kingdom is the Medicines and Healthcare Products Regulatory Agency. In June, 2012, the MHRA reported that the R3 metal liner demonstrated a higher revision rate, at 6.4% at four years, than non-metal liners. Moreover, the "high revision rate" exceeded the "4% guidance figure at four years from National Institute of Health and Clinical Excellence." Accordingly, the MHRA advised " surgeons to stop using the metal cup liner and to annually monitor the 281 patients who have been fitted with these cup liners so that any complications such as pain or swelling are picked up and treated early."

38. In June, 2012 the United States Food and Drug Administration organized a meeting of doctors and scientists to consider the risks and benefits of so-called "metal on metal" hip replacement systems. Important weight-bearing and moving parts in these designs are constructed entirely of metal, instead of ceramic.

39. The FDA panel did not find that the "metal on metal" systems provided significant benefits to the thousands of American patients who rely on them.

40. Despite knowledge that the R3 Acetabular system and metallic liner was causing adverse health effects and had a high revision rate, the Defendants continued to manufacture,

assemble, package, promote, label, market, distribute and sell the hip replacement system, known as the R3 Acetabular System.

41. On April 29, 2009, Plaintiff Walter Shuker underwent right primary total hip arthroplasty ("right hip replacement surgery") at the Surgical Institute of Reading. Kevin Terefenko, M.D. performed the surgery and installed a Smith & Nephew R3 acetabular shell with the metal liner.

42. Approximately 21 months after surgery, Plaintiff Walter Shuker began developing increasing buttocks, groin and thigh discomfort which caused him pain and extremely limited his daily activities.

43. Mr. Shuker underwent an aspiration procedure on May 23, 2011 at the Surgical Institute of Reading. Dr. Terefenko performed the surgery and discovered a milky brown tinged fluid and metallic debris which was removed from Plaintiff Shuker. Dr. Terefenko determined that the pain was caused by metal sensitivity due to the degeneration of the metal on metal articulation. He decided that replacement of the metal on metal articulation was necessary to relieve the pain caused by the R3 system.

44. On July 6, 2011, Plaintiff Walter Shuker underwent another surgery on his right hip at the Surgical Institute of Reading to replace the metal on metal articulation of the R3 system with an Oxinium head and polyethylene liner. The procedure was performed by Dr. Kevin Terefenko.

45. Post-surgery, Plaintiff Walter Shuker again developed extreme pain in the right hip area. Plaintiff Shuker presented at Lehigh Valley Hospital on November 2, 2012 with pain in his right hip. An aspiration procedure was performed by Dr. Terefenko on November 12, 2012 to determine the cause of the pain. It was determined that he had developed an infection at the site

of surgery on his right hip.

46. On December 7, 2012, Paul Pollice, M.D. performed an explant of Plaintiff Walter Shuker's right total hip replacement to remove the R3 acetabular system for eventual replacement.

47. On January 28, 2013, Plaintiff Walter Shuker underwent a third surgery, a right total hip replacement surgery, to replace the R3 Acetabular sytem.

48. The Defendants designing, developing, testing, manufacturing, assembling, packaging, promoting, labeling, marketing, distributing and selling the hip replacement system, known as the R3 Acetabular System, which was defective in its design, defective in its warnings, and defective in its manufacture caused Plaintiff Walter Shuker pain and suffering which necessitated multiple surgeries and continuing medical attention into the future.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
NEGLIGENCE/ NEGLIGENCE PER SE
COUNT I

49. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint.

50. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of the R3 Acetabular System into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

51. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the R3 Acetabular System into the interstate commerce in that Defendants knew or should have known that using the R3 Acetabular System created a high

risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery to repair, remove and/or replace the R3 Acetabular System, as well as other severe and permanent health consequences.

52. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Designing and manufacturing the R3 Acetabular System without thoroughly testing it;

(b) Not conducting sufficient testing programs to determine whether or not the aforesaid R3 Acetabular System was safe for use; in that Defendants herein knew or should have known that the R3 Acetabular System was unsafe and unfit for use by reason of the dangers to recipients;

(c) Selling the R3 Acetabular System without making proper and sufficient tests to determine the dangers to recipients;

(d) Negligently failing to adequately and correctly warn Plaintiff Walter Shuker, the public, the medical and healthcare profession, and/or the FDA of the dangers of the R3 Acetabular System;

(e) Negligently failing to recall their dangerous and defective R3 Acetabular Systems at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the R3 Acetabular System;

(g) Failing to test the R3 Acetabular System and/or failing to adequately, sufficiently and

properly test the R3 Acetabular System;

(h) Negligently advertising and recommending the use of the aforesaid R3 Acetabular System without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that the R3 Acetabular System was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that the R3 Acetabular System had equivalent safety and efficacy as other, non-defective total hip replacement systems;

(k) Negligently designing the R3 Acetabular System in a manner which was dangerous to its recipients;

(l) Negligently manufacturing the R3 Acetabular System in a manner which was dangerous to its recipients;

(m) Negligently producing the R3 Acetabular System in a manner which was dangerous to its users;

(n) Negligently assembling the R3 Acetabular System in a manner which was dangerous to its recipients; and

(o) Concealing information regarding tests, and/or reports, and/or studies from the Plaintiff and ~~her~~ His physicians, demonstrating that the R3 Acetabular System was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(p) Improperly concealing information from and/or misrepresenting information to the Plaintiff, healthcare professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the R3 Acetabular System;

(q) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the R3 Acetabular System; and

(r) Failing to provide reasonable assurance with respect to the safety and effectiveness of the R3 Acetabular System.

53. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

54. Defendants under-reported, underestimated and downplayed the serious dangers of the R3 Acetabular System.

55. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the R3 Acetabular System in that they:

(a) Failed to use due care in designing and manufacturing the R3 Acetabular System so as to avoid the aforementioned risks to individuals when the R3 Acetabular System was used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the R3 Acetabular System;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the R3 Acetabular System;

(d) Failed to warn Plaintiff Walter Shuker and his healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the R3 Acetabular System;

(f) Failed to warn Plaintiff Walter Shuker and his healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the R3 Acetabular System, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

56. Defendants knew or should have known that consumers such as Plaintiff Walter Shuker would suffer foreseeable injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

57. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

58. Defendants' negligence was the proximate cause of Plaintiff Walter Shuker's injuries, harm, and economic loss which he suffered and/or will continue to suffer.

59. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, as well as other severe and permanent health consequences.

60. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff Walter Shuker is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff Walter Shuker prays this Honorable Court find judgment in favor of Plaintiffs and against Defendants for an amount greater than $50,000 and for all

remedies available for negligence as provided by law.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
STRICT PRODUCT LIABILITY
COUNT II

61. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint.

62. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the R3 Acetabular System as hereinabove described and Plaintiff Walter Shuker was a recipient of said product.

63. The R3 Acetabular System was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

64. At all relevant times, the R3 Acetabular System was in an unsafe, defective, and inherently dangerous condition, which was dangerous to recipients, and in particular, Plaintiff Walter Shuker.

65. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the R3 Acetabular System.

66. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary healthcare provider would expect.

67. At all times herein mentioned, the R3 Acetabular System was in a defective condition and unsafe, and Defendants knew, or had reason to know, that said product was defective and unsafe, especially when used in the form and manner as provided by the defendants.

68. Defendants knew, or should have known, that at all times herein mentioned, the R3 Acetabular System was in a defective condition, and was inherently dangerous and unsafe.

69. At the time of Plaintiff Walter Shuker's receipt and/or use of the R3 Acetabular System, the R3 Acetabular System was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

70. Defendants, with this knowledge, voluntarily designed the R3 Acetabular System in a dangerous condition for use by the public, and in particular Plaintiff Walter Shuker and/or his healthcare professionals.

71. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

72. Defendants created a product unreasonably dangerous for its normal, intended use.

73. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that said R3 Acetabular System left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

74. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' R3 Acetabular System was manufactured.

75. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff Walter Shuker's in particular, and Defendants are therefore strictly liable for the injuries sustained by the plaintiff.

76. Plaintiff Walter Shuker could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

77. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery to repair, as well as other severe and permanent health consequences, and the Defendants failed to adequately warn of said risk.

78. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

79. The R3 Acetabular System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery to repair, remove and/or replace the R3 Acetabular System, as well as other severe and permanent health consequences, and Defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

80. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product, the R3 Acetabular System.

81. Defendants' defective design, manufacturing defect, and inadequate warnings of the R3 Acetabular System were acts that amount to willful, wanton, and/or reckless conduct by defendants.

82. That said defects in Defendants' R3 Acetabular System were substantial factors in causing Plaintiffs' injuries.

83. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, as well as other severe and permanent health consequences.

84. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff Walter Shuker is informed and believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff Walter Shuker prays this Honorable Court find judgment in favor of Plaintiffs and against Defendants for an amount greater than $50,000 and for all remedies available for strict product liability as provided by law.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
BREACH OF EXPRESS WARRANTY
COUNT III

85. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. Defendants expressly warranted that the R3 Acetabular System was safe and/or well accepted by users.

87. The R3 Acetabular System does not conform to these express representations because the R3 Acetabular System is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff Walter Shuker suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

88. Plaintiff Walter Shuker did rely on the express warranties of the Defendants herein.

89. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of the R3 Acetabular System in total hip replacement surgeries.

90. Defendants herein breached the aforesaid express warranties, as their R3 Acetabular Systems were defective.

91. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the R3 Acetabular System was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

92. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the R3 Acetabular System was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

93. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, as well as other severe and permanent health consequences.

94. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff Walter Shuker is informed and believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff Walter Shuker prays this Honorable Court find judgment in favor of Plaintiffs and against Defendants for an amount greater than $50,000 and for all remedies available for breach of warranty as provided by law.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY
COUNT IV

95. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint.

96. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the R3 Acetabular System, which is used in total hip replacement surgeries. At the time Defendants marketed, sold, and distributed the R3 Acetabular System for use by Plaintiff Walter Shuker, Defendants knew of the use for which the R3 Acetabular System was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

97. Defendants impliedly represented and warranted to the users and their physicians, healthcare providers, and/or the FDA that the R3 Acetabular System was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

98. That said representations and warranties aforementioned were false, misleading and inaccurate in that the R3 Acetabular System was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

99. Plaintiff, and members of the medical community, did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

100. Plaintiff and his physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the R3 Acetabular System was of merchantable quality and safe and fit for its intended use.

101. The R3 Acetabular System was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

102. Defendants herein breached the aforesaid implied warranties, as their R3 Acetabular Systems were not fit for their intended purposes and uses.

103. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker was, and/or still is, caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, as well as other severe and permanent health consequences.

104. As a result of the foregoing acts and omissions, Plaintiff Walter Shuker requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff Walter Shuker is informed and believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Pursuant to 13 Pa. Cons. Stat. Ann. §2314, Plaintiff Walter Shuker prays this Honorable Court find judgment in favor of Plaintiffs and against Defendants for all breach of warranty damages as provided by law.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
FRAUD

COUNT V

105. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint.

106. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of the Hip Replacement Devices, owed a duty not to deceive the Plaintiff Walter Shuker, health care providers and the public regarding the character, safety, quality and/or effectiveness of their medical devices.

107. Defendants, through studies and reports, received notice that their Hip Replacement Devices were prone to premature failure, causing patients to experience additional pain and injury. Defendants were informed that the metal-on-metal design of the Affected Products was capable of producing large volumes of metallic debris as the femoral head rotated and rubbed against the acetabular cup. Defendants were aware that these particles had been known to damage muscles, tendons and other soft tissue; were aware that these particles could interfere with the intended bone growth into the porous shell; were aware that many of these complications had necessitated early removal of the Affected Products and that the complications might make these revisions more complicated.

108. Despite this knowledge, Defendants continued to manufacture, distribute and promote the sale of their Hip Replacement Devices and willfully deceived Plaintiff Walter Shuker and ~~her~~ His medical providers as to the health risks associated with the Affected Product.

109. Defendants willfully concealed, misrepresented, suppressed and omitted material scientific and medical information about the risks of the Affected Products with the intent to defraud Plaintiff Walter Shuker.

110. Plaintiff Walter Shuker was unaware and ignorant of the falsity and/or incompleteness of the statements made by Defendants and reasonably relied upon them to be true.

111. Similarly, Dr. Terefenko was unaware of the falsity and/or incompleteness of the statements and/or incompleteness of the statements made by Defendants and reasonably relied upon them to be true.

112. Plaintiff Walter Shuker directly and/or indirectly reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

113. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff Walter Shuker sustained the injuries and damages heretofore alleged.

114. Defendants' conduct was malicious and a deliberate disregard for the rights and safety of others, including Plaintiff Walter Shuker, thereby entitling him to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff Walter Shuker prays this Honorable Court find judgment in favor of Plaintiffs and against Defendants for all remedies available as provided by law.

WALTER SHUKER, ET. AL V. SMITH & NEPHEW PLC, ET AL.
LOSS OF CONSORTIUM
COUNT VI

115. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint.

116. As a direct/ or proximate result of the Defendants' Actions, Plaintiff Walter Shuker has been caused to suffer great mental and emotional distress and loss of life' enjoyment which continue into the future.

117. At all times material to this action, Plaintiff Vivian Shuker was the lawful wife of Plaintiff Walter Shuker.

118. As a direct/ or proximate result of the Defendants' actions, Plaintiff Vivian Shuker has been caused to suffer loss of consortium, marital services and/or companionship of her spouse.

WHEREFORE, Plaintiffs Walter and Vivian Shuker pray this Honorable Court find judgment in favor of them and against Defendants for all remedies available as provided by law.

ZAJAC, ARIAS & TRICHON, P.C.

Eric Zajac, Esq.
ID # 66003
1835 Market Street, 26th Floor
Philadelphia, PA
19103
215-575-7615
Attorney for Plaintiffs

VERIFICATION

We, Walter and Vivian Shuker, having read the attached Complaint, verify that it is based on information furnished to counsel, which information has been gathered by counsel in connection with this lawsuit. *The language of the Complaint is that of our attorneys and is not ours.* We verify that we have read the Complaint and that it is true and correct to the best of our knowledge, information, and belief. To the extent that the contents of the Complaint represent the work of our attorneys, we have relied upon them in making this verification. This verification is made subject to the penalties of 18 Pa.C.S.A. § 4904 relating to unsworn falsification to authorities.

Date: 9-20-13

Walter Shuker
Walter Shuker

Date: 9-20-13

Vivian Shuker
Vivian Shuker